

5. 510(k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: December 30, 2011
Applicant: Solana Surgical, LLC
6363 Poplar Ave, Suite 434
Memphis, TN 38119

Common Name:	Toe joint, phalangeal (hemi-toe) prosthesis
Device Trade Name:	Hemi Phalangeal Implant System
Device Classification Name:	Toe joint phalangeal (hemi-toe) polymer prosthesis
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	21 CFR 888.3730
Product Code:	KWD
Predicate Device:	K023684 Vilex, K023770 Kinetikos Medical

Device Description:

The Solana Surgical Implant is a one-piece device made of Cobalt Chromium (with titanium plasma spray coated stem) intended to replace the articulating surface of the phalangeal bone at the metatarsalphalangeal (MTP) joint. The implant is available in a range of sizes (3) to match the geometry of the metatarsal phalangeal joint. Design features include an articulating surface and a stem which extends distally in the intramedullary canal of the proximal phalanx. The design of the Solana Surgical implant is similar to the predicate devices. No new materials or processes are used in the development of this implant.

Indications for Use:

The Solana Surgical LLC, Hemi Phalangeal Implant System is intended for use as a hemi-arthroplasty implant for the metatarsalphalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsalphalangeal (MTP) joint.

The device is intended for single use to be used with bone cement or press fit without bone cement.

Comparison to Predicate Device:**Summary:**

Similarities of the Solana Surgical device to its predicates include these devices being: intended for single use only, intended for surgical implantation longer than 30 days, system consisting of a series of implants, made of industry standard materials, with no new materials being introduced in the product, comparably sized, and indicated for the same uses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Solana Surgical, LLC.
% Ms. Louise Focht
Vice President Quality and Regulatory
6363 Poplar Avenue, Suite 434
Memphis, Tennessee 38119

FEB - 6 2012

Re: K120029

Trade/Device Name: Hemi Phalangeal Implant System

Regulation Number: 21 CFR 888.3730

Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis

Regulatory Class: Class II

Product Code: KWD

Dated: December 30, 2011

Received: January 4, 2012

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120029

Device Name: Hemi Phalangeal Implant System

Indications for Use:

The Solana Surgical LLC, Hemi Phalangeal Implant System is intended for use as a hemi-arthroplasty implant for the metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The device is intended for single use to be used with bone cement or press fit without bone cement.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division Sign-Off

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120029